

**REMARKS**

The Office Action mailed March 15, 2006 has been carefully considered and this paper is responsive thereto. Claims 1-53 are pending in the application. Claims 20, 40, 43, 46 and 53, drawn to a non-elected invention, have been withdrawn from consideration.

Claims 47 and 49 have been amended in step (i) to state that the homogeneous molten composition is highly viscous. Support for this amendment can be found, for example, in the specification at page 2, lines 1-2. Claim 14 has been canceled without prejudice. Claims 18-20, 34, 38, 39, 41 and 44 have been amended as discussed below.

At page 2 of the Office Action the Examiner restricted the claims under 35 USC 121 and required Applicants to elect species for various materials recited in the claims. The claims were restricted into two groups as follows:

Group I: Claims 1-19, 21-39, 41, 42, 44-45 and 47-52, drawn to a process, classified in class 264; and

Group II: Claims 20, 40, 43, 46 and 53, drawn to a product, classified in class 428.

The grouping of claims is different than the grouping of claims presented to Applicants' representative Liza Hohenschutz by the Examiner during a telephone interview on February 10, 2006. At that time the restriction requirement was presented as six groups of claims. On February 14, 2006 during another telephone interview, Applicants' representative advised the Examiner that Applicants elected Group III (claims 21-39, 41-43 49 and 50) for prosecution with the following species: hydrocolloid – carrageenan, plasticizer – glycerin, second film former – starch derivative, bulking agent – starch hydrolyzate and type of capsules – soft capsules. In the present Office Action, the claims of Group III, except for claim 43, are placed in Group I.

Applicants elect the invention of Group I (Claims 1-19, 21-39, 41, 42, 44-45 and 47-52) for prosecution without traverse. Applicants also elect the following species: hydrocolloid - carrageenan; plasticizer – glycerin; second film former – starch derivative and bulking agent – starch hydrolyzates.

At page 3 of the Office Action, the Examiner rejected claims 4-8 and 24-28 under 35 USC 112, second paragraph as being indefinite. The Examiner alleges that the claims are

indefinite because claims 1 and 21 state that the molten composition is a “homogeneous molten composition”, whereas claims 4-8 and 24-28 state that the molten composition is partially solids.

Applicants traverse this rejection. As explained in the specification, a homogeneous molten composition contains both soluble and insoluble materials, wherein the soluble materials are dissolved and the insoluble materials are distributed. The specification as page 6, lines 11-14 explains that the “solubilizing temperature” means the temperature at which the composition becomes homogeneous, and that solubilizing refers to the act of fully dissolving all the soluble components in the molten composition and all insoluble materials are uniformly dispersed. Claims 4-8 and 24-28 properly depend from claims 1 and 21, respectively, because the homogeneous molten compositions of claims 1 and 21 include solids. The term “homogeneous molten composition” is thus not indefinite and withdrawal of this section 112, second paragraph rejection is respectfully requested.

At page 4 of the Office Action, the Examiner objected to claims 14, 18-20 and 38-46 under 37 CFR 1.75(c) as being in improper form because a multiple dependent claims should refer to other claims in the alternative only and a multiple dependent claim cannot depend from any other multiple dependent claim (MPEP § 608.01(p)).

Claim 14 has been canceled without prejudice. Claims 18 and 19 have been amended to depend from claim 1. Claim 34 has been amended to depend from claim 21. Claims 38 and 39 have been amended to depend from claim 21. Claims 41 and 44 have been amended to depend from any one of claims 1-13 or 15-19. Withdrawal of this objection to the claims is respectfully requested.

At page 4 of the Office Action, the Examiner rejected claims 1, 2, 3, 9-13, 15, 16, 21, 22, 23, 29-33, 35, 36, 47, 49 and 51-52 under 35 USC 102(b) as anticipated by Gennadios (U.S. Patent 6,214,376).

Applicants traverse this rejection.

Gennadios discloses compositions useful for preparing gelatin-free capsules for oral administration of medicines, cosmetic or bath applications, or dietary supplements and methods for preparing the compositions. The compositions are disclosed to contain 0.5 to 12% by weight of kappa carrageenan, where the kappa carrageenan comprises at least 50% by weight of all film-forming material in the composition, 8-50% by weight of water-dispersible or water-soluble

plasticizer; 0 to 60% dextrans, and 1% to 95% by weight water. Gennadios also discloses methods for preparing films from the compositions at column 6, lines 39-68. In the methods, a working composition is heated, preferably with stirring, to above 130°F to below the boiling point of the working mixture. The heated working composition is then transferred or introduced for processing to a conventional gelatin encapsulation machine. Films are formed by casting the solution on cooled rotating drums. Column 6, lines 1-4 state that when the compositions are prepared at room temperature, they are a very viscous mass (often dough-like), and upon heating, the mass “thins out” and is converted to a clear free-flowing liquid.

Gennadios does not anticipate claims 1, 2, 3, 9-13, 15, 16, 21, 22, 23, 29-33, 35, 36, 47, 49 and 51-52.

Claim 1 is directed to a process for making homogeneous, thermoreversible gel films comprising the steps of: (i) heating, hydrating, mixing, solubilizing, and, optionally, de-aerating a film forming composition in an apparatus providing sufficient shear, temperature and residence time to form a homogeneous molten composition, wherein the temperature is at or above the solubilizing temperature of the composition; (ii) feeding the molten composition into at least one of a mixer, pump or devolatilizer; and (iii) cooling the homogeneous molten composition at or below its gelling temperature to form the gel films. There is no disclosure in Gennadios of step (ii) of claim 1, feeding the molten composition into at least one of a mixer, pump or devolatilizer. Gennadios does not disclose each and every limitation of claim 1 and thus does not anticipate claim 1. Claims 2, 3, 9-13, 15, 16, 51 and 52 depend directly or indirectly from claim 1 and are also not anticipated by Gennadios.

Claim 21 is directed to a process for making soft capsules comprising the steps of: (i) heating, hydrating, mixing, solubilizing and, optionally, de-aerating a high solids, low moisture film forming composition in an apparatus providing sufficient shear, temperature and residence time to form a homogeneous molten composition, wherein the temperature is at or above the solubilizing temperature of the composition; (ii) feeding the molten composition into at least one of a mixer, pump or devolatilizer; (iii) cooling the molten composition to or below the gelling temperature of the molten composition to form a homogeneous, thermoreversible gel film; and (iii) making soft capsules from the gel film. There is no disclosure in Gennadios of step (ii) of claim 21, feeding the molten composition into at least one of a mixer, pump or devolatilizer.

Gennadios does not disclose each and every limitation of claim 21 and thus does not anticipate claim 21. Claims 22, 23, 29-33, 35 and 36 depend directly or indirectly from claim 21 and are also not anticipated by Gennadios.

Claim 47 is directed to a process for making homogeneous, thermoreversible gel films comprising the steps of: (i) heating, hydrating, mixing, solubilizing, and, optionally, deaerating a film forming composition in an apparatus providing sufficient shear, temperature and residence time to form a highly viscous homogeneous molten composition, wherein the temperature is at or above the solubilizing temperature of the composition; and (ii) cooling the homogeneous molten composition at or below its gelling temperature to form the gel films. Column 4, lines 1-4 of Gennadios state that when the working composition is prepared at room temperature, it is a very viscous mass (often dough-like), and upon heating, the mass “thins out” and is converted to a clear free-flowing liquid. In contrast to Gennadios, in the method of amended claim 47, the homogeneous molten composition is highly viscous after heating. Gennadios does not disclose each and every limitation of claim 47 and thus does not anticipate claim 47.

Claim 49 is directed to a process for making soft capsules comprising the steps of: (i) heating, hydrating, mixing, solubilizing and, optionally, deaerating a high solids, low moisture film forming composition in an apparatus providing sufficient shear, temperature and residence time to form a highly viscous homogeneous molten composition, wherein the temperature is at or above the solubilizing temperature of the composition; (ii) cooling the molten composition to or below the gelling temperature of the molten composition to form a homogeneous, thermoreversible gel film; and (iii) making soft capsules from the gel film. As discussed above, column 6, lines 1-4 of Gennadios state that when the working composition is prepared at room temperature, it is a very viscous mass (often dough-like), and upon heating, the mass “thins out” and is converted to a clear free-flowing liquid. In contrast to Gennadios, in the method of amended claim 49 the homogeneous molten composition is highly viscous after heating. Gennadios does not disclose each and every limitation of claim 49 and thus does not anticipate claim 49.

Withdrawal of this section 102(b) rejection is respectfully requested.

At page 8 of the Office Action, the Examiner rejected claims 17 and 37 under 35 USC 103 as being unpatentable over Gennadios (U.S. Patent 6,214,376) as applied to claims 1 and 21

in the previous rejection. The Examiner alleges that it would have been obvious to a person of ordinary skill in the art at the time of the invention to optimize the process by increasing the pressure to above atmospheric pressure during the formation of the homogeneous molten composition in order to decrease the time required for formation of the desired composition.

Applicants traverse this rejection. Gennadios was discussed above. Briefly, Gennadios discloses compositions useful for preparing gelatin-free capsules that are disclosed to contain 0.5 to 12% by weight of kappa carrageenan, where the kappa carrageenan comprises at least 50% by weight of all film-forming material in the composition, 8-50% by weight of water-dispersible or water-soluble plasticizer; 0 to 60% dextrins, and 1% to 95% by weight water. Gennadios also discloses methods for preparing films from the compositions at column 6, lines 39-68. In the methods, a working composition is heated, preferably with stirring, to above 130°F to below the boiling point of the working mixture. The heated working composition is then transferred or introduced for processing to a conventional gelatin encapsulation machine. Films are formed by casting the solution on cooled rotating drums.

Claims 17 and 37 are directed to the processes of claims 1 and 21, respectively, wherein the solubilizing temperature is greater than the boiling point of the homogeneous molten composition at atmospheric pressure and the heating, hydrating, mixing and solubilizing is conducted above atmospheric pressure.

Gennadios provides no disclosure, suggestion or motivation to vary the pressure at which the working composition is heated. There is no disclosure or suggestion in Gennadios of heating the working composition at pressures above atmospheric pressure. Moreover, Gennadios provides no guidance nor identifies a need or reason to vary the pressure at which heating of the working composition is conducted. In the absence of any disclosure, suggestion or motivation, a person skilled in the art would not be led by the teachings of Gennadios to heat the working composition at a pressure greater than atmospheric pressure. Claims 17 and 34 are not obvious in view of Gennadios. Withdrawal of this section 103 rejection is respectfully requested.

At page 9 of the Office Action, the Examiner rejected claims 48 and 50 under 35 USC 103 as being unpatentable over Gennadios (U.S. Patent 6,214,376) as applied to claims 47 and 49, respectively, and further in view of Thanoo (U.S. Patent 5,945,126). The Examiner alleges that it would have been obvious at the time of the invention for a person of ordinary skill in the

art to utilize a Ross Mixer as the apparatus in the process of Gennadios, as taught by Thanoo, in order to control the mixing intensity independently of the flow rates of the feed streams.

Applicants traverse this rejection.

Gennadios was discussed above. Briefly, the films in Gennadios are formed by heating a working composition, preferably with stirring, to above 130°F to below the boiling point of the working mixture. The heated working composition is then transferred or introduced for processing to a conventional gelatin encapsulation machine. Films are formed by casting the solution on cooled rotating drums.

Thanoo discloses a continuous process for producing microspheres wherein small particle sizes can be obtained without the problem of foaming. A drug and polymer containing dispersed phase is continuously introduced into a high intensity emulsification vessel along with a continuous phase. An emulsion of the dispersed phase is formed in the continuous phase by high intensity mixing is effective to quickly solidify the dispersed phase polymer without having to take steps to address foaming. Ross mixers are disclosed at column 12, line 13-40 as a suitable type of high turbulence intensity emulsification vessel that can be used in the methods disclosed therein.

Claims 48 and 50 are directed to the methods of claims 47 and 49, respectively, wherein the apparatus used in the step of heating, hydrating, mixing, solubilizing and, optionally, deaerating the high solids, low moisture film forming composition is a Ross mixer.

Claims 48 and 50 are not obvious over the combined teachings of Gennadios and Thanoo. That is, there is no teaching, suggestion or motivation in Gennadios or Thanoo, alone or in any combination, to combine the teaching of a Ross mixer with the method of Gennadios. There is no teaching or suggestion in Gennadios to use a Ross mixer. Gennadios suggests stirring the working composition, but there is no disclosure or suggestion of using a Ross mixer. Thanoo is concerned with a process of preparing microspheres wherein small particle sizes can be formed without the problem of foaming. A Ross mixer is disclosed as a useful type of mixer for the process therein. There is no disclosure or suggestion in Thanoo of using the Ross mixer for purposes other than the process disclosed therein, much less using a Ross mixer in a process with a film forming composition wherein a highly viscous homogeneous molten composition is formed. It is impermissible to pick and choose from any one reference only so much of it as will

support a given position to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one skilled in the art.

Withdrawal of this section 103 rejection is respectfully requested.

In view of the above, the present application is believed to be in a condition ready for allowance. Reconsideration of the application is requested and an early Notice of Allowance is earnestly solicited.

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 03-2775, under Order No. 10884-00008-US. A duplicate copy of this paper is enclosed.

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Respectfully submitted,

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